

**MEDICAL USE OF RADIOACTIVE MATERIAL UNDER GENERAL LICENSE  
CONDITIONS AND LIMITATIONS OF GENERAL LICENSE S 4.22-H** (continued)

S 4.22-G. Manufacture and Distribution of Radioactive Material for Medical Use Under General License. In addition to requirements set forth in S 4.25, a specific license authorizing the distribution of radioactive material for use by physicians under the general license in S 4.22-H will be issued if:

1. the applicant submits evidence that radioactive material is to be manufactured, labeled, and packaged in accordance with a new drug application which the commissioner for Food and Drugs, Food and Drug Administration, has approved, or in accordance with a license for a biologic product issued by the Secretary, Department of Health and Human Services; and
2. one of the following statements, as appropriate, or substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package.
  - a. This radioactive drug may be received, possessed, and used only by physicians licensed to dispense practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

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Name of Manufacturer

- b. This radioactive drug may be received, possessed, and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of a Licensing State.

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Name of Manufacturer

Note: if larger quantities or other forms of radioactive material than those specified in the general license of S 4.22-H are required, the physician should file an "Application for Radioactive Material License", Form RH-F-4 and obtain a specific radioactive material license. Copies of application and certification forms may be obtained from: Va. Health Dept., Radiological Health, P.O. Box 2448, Richmond, VA 23219.